REMARKS

Claim 1 as presented with applicants' paper dated July 10, 2006, is currently pending in this case.

The Examiner rejected Claim 1 under 35 U.S.C. §102(b) as being anticipated by the teaching of ***Watanabe et al.*** **(US 5,650,433)**. Favorable reconsideration of the Examiner's position and withdrawal of the respective rejection is respectfully solicited.

It is well settled that anticipation under Section 102 can be found only if a reference shows exactly what is claimed. This means that all material elements of the invention as claimed must be found in one prior art source,[1] the claim elements must be shown in the reference in as much detail as is contained in the claim,[2] and the claim elements must be shown in the reference in the part-to-part relationship which is set forth in the claim.[3]

Applicants' Claim 1 is drawn to a *"neutraceutical composition for inhibiting COX-2 biosynthesis or COX-2- and NFχB-biosynthesis"* which comprises *"a therapeutically effective amount"* of a certain *"compound of formula I"* and *"a pharmaceutically acceptable carrier."*

As noted by the Examiner *"the definition of neutraceutical defines the term a food or naturally occurring food supplement that has a beneficial effect on health."*[4] Additionally, applicants specify that a neutraceutical is *"a composition which includes only naturally occurring components capable of providing beneficial therapeutic and health promoting effects."*[5]

The Examiner argued that applicants' reference to a neutraceutical composition was merely an indication of an intended use, and was, as such, not given weight in the determination of patentability. However, the characterization as a *"food or naturally occurring food supplement"* or as including *"only naturally occurring components ca-*

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1) Cf. *In re Marshall*, 577 F.2d 301, 198 USPQ 344 (CCPA 1978); *In re Kalm*, 378 F.2d 959, 154 USPQ 10 (CCPA 1967).

2) Cf. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989).

3) Cf. *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984).

4) Final Office action page 3, lines 1 to 3.

5) Cf. page 9, indicated lines 26 to 30, of the application.

pable of providing beneficial therapeutic and health promoting effects" clearly imparts boundaries to the nature of the constituents of applicants' composition, and any terminology in the preamble which limits the structure of the claimed invention must be treated as a claim limitation.[6] Accordingly, applicants' reference to a *"neutraceutical composition"* in the preamble of Claim 1 cannot be disregarded in a determination under Section 102.

The teaching of ***Watanabe et al.*** fails to show all material elements of applicants claim in the detail and exactness which is required for a finding of anticipation under Section 102. The reference addresses a chondroprotective agent for reducing or suppressing the destruction of the articular cartilage in a patient suffering from arthropathy.[7] The active ingredient may be any one of a number of flavonoid compounds as represented by the formula set forth in col. 2, indicated lines 27 to 44, of the reference. The reference also provides a list of 51 illustrated representative examples of suitable compounds which list includes the compound represented by applicants' formula (I),[8] and states that the chondroprotective agent containing such active substance may be in the form of any conventional formulation, and may contain the active substance alone or in mixture with any pharmaceutically acceptable carrier or diluent.[9] Illustrative investigations which are summarized in the reference do not include a description of preparations in which the active substance was substance No. 1 of the reference, ie. the compound corresponding to applicants' formula (I),[10] and the formulations of active substances which are described in the reference are clearly outside of the realm of neutraceuticals.[11]

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6) See, eg., *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989) (The determination of whether preamble recitations are structural limitations can be resolved only on review of the entirety of the application "to gain an understanding of what the inventors actually invented and intended to encompass by the claim."); *Pac-Tec Inc. v. Amerace Corp.*, 903 F.2d 796, 801 (Fed. Cir. 1990) (determining that preamble language that constitutes a structural limitation is actually part of the claimed invention). See also *In re Stencel*, 828 F.2d 751, 754 (Fed. Cir. 1987) ("[T]he framework - the teachings of the prior art - against which patentability is measured is not all drivers broadly, but drivers suitable for use in combination with this collar, for the claims are so limited.").

7) Eg. col. 2, indicated lines 10 to 19, and and col. 5, indicated lines 4 to 14, of ***US 5,650,433***.

8) Cf. cols. 3 and 4 of ***US 5,650,433***.

9) Cf. col. 5, indicated lines 14 to 20, of ***US 5,650,433***.

10) Cf. col. 6, indicated lines 15 to 25, of ***US 5,650,433***.

11) Cf. col. 7, indicated lines 50 to 55, of ***US 5,650,433***.

The reference fails to show exactly what is claimed by applicants because not all of the material elements of applicants' claim can be found in the reference: The teaching of ***Watanabe et al.*** fails to show any composition which can reasonably be regarded as a neutraceutical.

The reference also fails to show exactly what is claimed by applicants because the elements of applicants' invention are not shown in the reference in as much detail as is contained in Claim 1. The teaching of ***Watanabe et al.*** not only fails to show any composition which can reasonably be regarded as a neutraceutical, but also fails to show any composition which contains substance No. 1 of the reference, ie. the compound corresponding to applicants' formula (I).

As outlined at the outset, anticipation under Section 102 requires more than a generic disclosure. The test for anticipation is one of identity which means that the identical invention must be shown in the reference in as complete detail as is contained in the claim. These circumstances for finding anticipation under Section 102 are clearly not met where the teaching of ***Watanable et al.*** and the subject matter of applicants' Claim 1 are concerned. It is therefore respectfully requested that the rejection be withdrawn. Favorable action is solicited.

For completeness sake it is further respectfully submitted that the reference cannot be deemed to establish a *prima facie* case of obviousness under Section 103(a). To establish a *prima facie* case of obviousness three basic criteria have to be met:[12)]

(1) There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings,

(2) there must be a reasonable expectation of success, and

(3) the prior art reference or the combined references must teach or suggest all of the claim limitations.

Additionally, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and cannot be based on the applicant's disclosure.[13)] Also, when applying 35 U.S.C. 103, it is inter alia necessary that

12) Cf. MPEP §2143.

13) *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

any reference be considered as a whole without the benefit of impermissible hindsight vision afforded by the claimed invention, and that the reference suggest the desirability and thus the obviousness of making the claimed combination.[14)]

A person of ordinary skill in the art who is not imbued with knowledge about applicants' invention is directed by the teaching of ***Watanable et al.*** to pharmaceutics in any conventional formulation which may contain any pharmaceutically acceptable carrier. Such a person could clearly not find any hint in the reference that it would be desirable for the purposes of the chondroprotective agent to provide a preparation which meets the criteria of a neutraceutical. As such, the reference fails to meet the basic criterion that there has to be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to effect the modification which is necessary to arrive at the claimed invention.

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14) *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).